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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEVADA

BAYER SCHERING PHARMA AG & BAYER HEALTHCARE PHARMACEUTICALS INC.,

Plaintiffs,

v.

LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,

Defendants.

Civil Case No. 2:10-cv-01166-GMN-RJJ

ANSWER AND COUNTERCLAIMS

Defendants Lupin Pharmaceuticals, Inc. ("LPI") and Lupin Limited (collectively, "Lupin") by and through their attorneys, respond to each of the numbered paragraphs in the Complaint by Plaintiffs Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. ("Plaintiffs") as follows:

PARTIES

1. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 of the Complaint and, therefore, denies them.

2. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Complaint and, therefore, denies them.

3. Lupin admits that Lupin Limited is a company organized and existing under the laws of India, has a place of business at Laxmi Towers "B" Wing, 5th Floor, Bandra Kurla Complex, Mumbai 400 051, India, and has a registered office at 159 C.S.T. Road, Kalina, Santacruz (East), Mumbai 400 098, India. Lupin further admits that Lupin Limited manufactures and sells pharmaceutical products through subsidiaries, including through LPI, but denies the remaining allegations in paragraph 3 of the Complaint.

4. Lupin admits that LPI is a corporation organized and existing under the laws of the State of Virginia, and has a place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Lupin further admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin denies the remaining allegations in paragraph 4 of the Complaint.

5. Lupin admits that Lupin Limited submitted ANDA No. 20-1661 to the U.S. Food and Drug Administration ("FDA") which seeks FDA approval to market the drospirenone and ethinyl estradiol product described in ANDA No. 20-1661 ("Lupin Limited's drospirenone and ethinyl estradiol tablets") in the United States. Lupin further admits that LPI or a designee plans to market Lupin Limited's drospirenone and ethinyl estradiol tablets in the United States as soon

as permitted to do so by the applicable statutes and regulations. Lupin denies the remaining allegations in paragraph 5 of the Complaint.

6. Lupin admits that LPI is designated as Lupin Limited's U.S. agent in connection with Lupin Limited's ANDA No. 20-1661 which seeks FDA approval to market Lupin Limited's drospirenone and ethinyl estradiol tablets in the United States. Lupin denies the remaining allegations in paragraph 6 of the Complaint.

JURISDICTION AND VENUE

7. For the purposes of this action only, Lupin does not contest subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). The remaining assertions in paragraph 7 comprise legal conclusions to which no answer is required. To the extent an answer to any factual allegation not otherwise addressed herein is required, Lupin denies said allegation.

8. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. The remaining assertions in paragraph 8 comprise legal conclusions to which no answer is required. To the extent an answer to any factual allegation not otherwise addressed herein is required, Lupin denies said allegation.

9. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 9 of the Complaint and, therefore, denies them.

10. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin. Lupin admits that LPI is a wholly-owned subsidiary of Lupin

Limited, and that LPI sells pharmaceutical products for the United States market, which includes the State of Nevada, and that residents of the State of Nevada may purchase drug products offered for sale by LPI. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 10 of the Complaint and, therefore, denies them.

11. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market, and that residents of the State of Nevada may purchase drug products offered for sale by LPI. Lupin denies any remaining allegations in paragraph 11 of the Complaint.

12. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market, which market includes the State of Nevada, and derives revenue from those sales. Lupin denies any remaining allegations in paragraph 12 of the Complaint.

13. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin denies any remaining allegations in paragraph 13 of the Complaint.

14. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin denies any remaining allegations in paragraph 14 of the Complaint.

15. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin denies any remaining allegations in paragraph 15 of the Complaint.

16. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI or a designee plans to market Lupin Limited's drospirenone and ethinyl estradiol tablets in the United States as soon as permitted to do so by the applicable statutes and regulations. Lupin denies the remaining allegations in paragraph 16 of the Complaint.

17. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over LPI. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market, which market includes the State of Nevada. The remaining assertions in Paragraph 17 comprise legal conclusions to which no answer is required. To the extent an answer to any factual allegation not otherwise addressed herein is required, Lupin denies said allegation.

18. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over LPI. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 18 of the Complaint and, therefore, denies them.

19. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over LPI. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market, which market includes the State of Nevada, and that residents of the State of Nevada may purchase drug products offered for sale by LPI. Lupin is without knowledge or information sufficient to form a

belief as to the truth of the remaining allegations in paragraph 19 of the Complaint and, therefore, denies them.

20. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over LPI. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market, and that residents of the State of Nevada may purchase drug products offered for sale by LPI. Lupin denies any remaining allegations in paragraph 20 of the Complaint.

21. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over LPI. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market and derives revenue from those sales, which market includes the State of Nevada. Lupin denies any remaining allegations in paragraph 21 of the Complaint.

22. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over LPI. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin denies any remaining allegations in paragraph 22 of the Complaint.

23. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over LPI. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin denies any remaining allegations in paragraph 23 of the Complaint.

24. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over LPI. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin denies any remaining allegations in paragraph 24 of the Complaint.

25. Lupin admits that or a designee plans to market Lupin Limited's drospirenone and ethinyl estradiol tablets in the United States as soon as permitted to do so by the applicable statutes and regulations. Lupin denies the remaining allegations in paragraph 25 of the Complaint.

26. For purposes of this action only, Lupin does not contest venue in this judicial district.

BACKGROUND

27. Lupin admits that the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" ("Orange Book") lists "Bayer Hlthcare" as the applicant in connection with Application No. N021676 (Proprietary Name: YAZ®), with the dosage form and active ingredient thereof being described in the Orange Book as "tablet" and "drospirenone, ethinyl estradiol," respectively. Lupin further admits that the 2010 Physician's Desk Reference states that YAZ® is indicated for the prevention of pregnancy in women who elect to use an oral contraceptive, for the treatment of symptoms of pre-menstrual dysphoric disorder (PMDD) in women who chose to use an oral contraceptive as their method of contraception, and for the treatment or moderate acne vulgaris in women at least 14 years of age, which have no known contraindications to oral contraceptive therapy and have achieved menarche. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 27 of the Complaint and, therefore, denies them.

28. Lupin admits that the dosage strength listed in the Orange Book for YAZ® is 3 mg and 0.02 mg of drospirenone and ethinyl estradiol, respectively. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 28 of the Complaint and, therefore, denies them.

29. Lupin admits that Lupin Limited submitted ANDA No. 20-1661 to the FDA which seeks approval to market Lupin Limited's drospirenone and ethinyl estradiol tablets described therein in the United States. Lupin denies the remaining allegations in paragraph 29 of the Complaint.

30. Lupin admits that each of Lupin Limited's drospirenone and ethinyl estradiol tablets contains, *inter alia*, 3.0 mg of drospirenone and 0.02 mg ethinyl estradiol. Lupin denies the remaining allegations in paragraph 30 of the Complaint.

31. Lupin admits that Lupin Limited submitted ANDA No. 20-1661 to the FDA seeking approval to market Lupin Limited's drospirenone and ethinyl estradiol tablets, and further that each tablet contains, *inter alia*, 3.0 mg of drospirenone and 0.02 mg ethinyl estradiol. Lupin denies the remaining allegations in paragraph 31 of the Complaint.

32. Lupin admits that on June 2, 2010, Lupin Limited sent letters to Bayer HealthCare Pharmaceuticals, Inc. and Bayer Schering Pharma Aktiengesellschaft pursuant to and in compliance with 21 U.S.C. § 355(j)(2)(B)(ii), informing them that Lupin Limited submitted ANDA No. 20-1661 to the FDA, and that this ANDA contains a Paragraph IV Certification with respect to U.S. Patent Nos. 5,569,652; 5,798,338; 6,787,531; 6,933,395; 6,958,326; 7,163,931; RE 37,564; RE 37,838; and RE 38,253, this certification asserting that these nine patents are invalid and/or will not be infringed by Lupin Limited's drospirenone and ethinyl estradiol tablets. Lupin denies any remaining allegations in paragraph 32 of the Complaint.

PATENTS-IN-SUIT

33. Lupin admits that the Complaint alleges three counts of patent infringement: (1) the infringement of U.S. Patent No. RE 37,564; (2) the infringement of U.S. Patent No. RE 37,838; and (3) the infringement of U.S. Patent No. RE 38,253.

34. Lupin admits that U.S. Patent RE 37,564 ("the '564 reissue patent") issued on February 26, 2002. Lupin further admits that the '564 reissue patent lists Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke as inventors, and that the '564 reissue patent lists a filing date of February 15, 2000. Lupin also admits that what Bayer asserts to be a copy of the '564 reissue patent is attached as Exhibit 1 to the Complaint. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 34 of the Complaint and, therefore, denies them.

35. Lupin admits that U.S. Patent No. RE 37,838 ("the '838 reissue patent") issued on September 10, 2002. Lupin further admits that the '838 reissue patent lists Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke as inventors, and that the '838 reissue patent lists a filing date of February 15, 2000. Lupin also admits that what Bayer asserts to be a copy of the '838 reissue patent is attached as Exhibit 2 to the Complaint. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 35 of the Complaint and, therefore, denies them.

36. Lupin admits that U.S. Patent No. RE 38,253 ("the '253 reissue patent") issued on September 16, 2003. Lupin further admits that the '253 reissue patent lists Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke as inventors, and that the '253 reissue patent lists a filing date of February 25, 2002. Lupin also admits that what Bayer asserts to be a copy of the '253 reissue patent is attached as Exhibit 3 to the Complaint. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 36 of the Complaint and, therefore, denies them.

COUNT ONE: CLAIM FOR PATENT INFRINGEMENT OF U.S. REISSUE PATENT NO. 37,564

37. Lupin incorporates by reference its responses to paragraphs 1 to 36 of the Complaint as if fully set forth herein.

38. Lupin denies that Lupin Limited's drospirenone and ethinyl estradiol tablets infringe any valid and enforceable claim of the '564 reissue patent.

39. Lupin admits that the Orange Book associates the '564 reissue patent with YAZ®. The remaining allegations in paragraph 39 of the Complaint state legal conclusions to which no answer is required. To the extent any factual assertions are included in the remaining allegations in paragraph 39 of the Complaint, Lupin denies them.

40. Lupin admits that Lupin Limited submitted ANDA No. 20-1661 to the FDA seeking approval to market Lupin Limited's drospirenone and ethinyl estradiol tablets in the United States prior to the expiration of the '564 reissue patent. Lupin further admits that LPI or a designee plans to market Lupin Limited's drospirenone and ethinyl estradiol product as soon as permitted to do so by the applicable statutes and regulations. Lupin denies any remaining allegations in paragraph 40 of the Complaint.

41. Lupin admits that ANDA No. 20-1661 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion, the '564 reissue patent is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Lupin Limited's drospirenone and ethinyl estradiol tablets. Lupin denies the remaining allegations in paragraph 41 of the Complaint.

42. Lupin denies that Lupin Limited's drospirenone and ethinyl estradiol tablets infringe any valid and enforceable claim of the '564 reissue patent. The remainder of paragraph 42 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 42 of the Complaint, Lupin denies them.

43. Paragraph 43 of the Complaint states legal conclusions and/or remedies sought to which no answer is required. To the extent any factual assertions are included in paragraph 43 of the Complaint, Lupin denies them.

44. Lupin admits that it was aware of the '564 reissue patent when it filed ANDA No. 20-1661. Lupin denies the remaining allegations in paragraph 44 of the Complaint.

COUNT TWO: CLAIM FOR PATENT INFRINGEMENT OF U.S. REISSUE PATENT NO. 37,838

45. Lupin incorporates by reference its responses to paragraphs 1 to 44 of the Complaint as if fully set forth herein.

46. Lupin denies that Lupin Limited's drospirenone and ethinyl estradiol tablets infringe any valid and enforceable claim of the '838 reissue patent.

47. Lupin admits that the Orange Book associates the '838 reissue patent with YAZ®. The remaining allegations in paragraph 47 of the Complaint state legal conclusions to which no answer is required. To the extent any factual assertions are included in the remaining allegations in paragraph 47 of the Complaint, Lupin denies them.

48. Lupin admits that Lupin Limited submitted ANDA No. 20-1661 to the FDA which seeks approval to market Lupin's drospirenone and ethinyl estradiol tablets in the United States. Lupin further admits that LPI or a designee plans to market Lupin's drospirenone and ethinyl estradiol product in the United States as soon as permitted to do so by any applicable statutes and regulations. Lupin denies the remaining allegations in paragraph 48 of the Complaint.

49. Lupin admits that ANDA No. 20-1661 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion, the '838 reissue patent is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Lupin Limited's drospirenone and ethinyl estradiol tablets. Lupin denies the remaining allegations in paragraph 49 of the Complaint.

50. Lupin denies that Lupin Limited's drospirenone and ethinyl estradiol tablets infringe any valid and enforceable claim of the '838 reissue patent. The remainder of paragraph

50 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 50 of the Complaint, Lupin denies them.

51. Paragraph 51 of the Complaint states legal conclusions and/or remedies sought to which no answer is required. To the extent any factual assertions are included in paragraph 51 of the Complaint, Lupin denies them.

52. Lupin admits that it was aware of the '838 reissue patent when it filed ANDA No. 20-1661. Lupin denies the remaining allegations in paragraph 52 of the Complaint.

COUNT THREE: CLAIM FOR PATENT INFRINGEMENT OF U.S. REISSUE PATENT NO. 38,253

53. Lupin incorporates by reference its responses to paragraphs 1 to 52 of the Complaint as if fully set forth herein.

54. Lupin denies that Lupin Limited's drospirenone and ethinyl estradiol tablets infringe any valid and enforceable claim of the '253 reissue patent.

55. Lupin admits that the Orange Book associates the '253 reissue patent with YAZ®. The remaining allegations in paragraph 55 of the Complaint state legal conclusions to which no answer is required. To the extent any factual assertions are included in the remaining allegations in paragraph 55 of the Complaint, Lupin denies them.

56. Lupin admits that Lupin Limited submitted ANDA No. 20-1661 to the FDA seeking approval to market Lupin Limited's drospirenone and ethinyl estradiol tablets in the United States prior to the expiration of the '253 reissue patent. Lupin further admits that LPI or a designee plans to market Lupin Limited's drospirenone and ethinyl estradiol product as soon as permitted to do so by the applicable statutes and regulations. Lupin denies any remaining allegations in paragraph 56 of the Complaint.

57. Lupin admits that ANDA No. 20-1661 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion, the '253 reissue patent is invalid, unenforceable

and/or will not be infringed by the manufacture, use or sale of Lupin Limited's drospirenone and ethinyl estradiol tablets. Lupin denies the remaining allegations in paragraph 57 of the Complaint.

58. Lupin denies that Lupin Limited's drospirenone and ethinyl estradiol tablets infringe any valid and enforceable claim of the '253 reissue patent. The remainder of paragraph 58 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 58 of the Complaint, Lupin denies them.

59. Paragraph 59 of the Complaint states legal conclusions and/or remedies sought to which no answer is required. To the extent any factual assertions are included in paragraph 59 of the Complaint, Lupin denies them.

60. Lupin admits that it was aware of the '253 reissue patent when it filed ANDA No. 20-1661. Lupin denies the remaining allegations in paragraph 60 of the Complaint.

AFFIRMATIVE AND SEPARATE DEFENSES

Without prejudice to the denials set forth in its responses to paragraphs 1 through 60 of the Complaint, Lupin alleges the following Affirmative and Separate Defenses to the Complaint.

First Defense
(Invalidity of the '564, '838, and '253 Reissue Patents)

61. The '564 reissue patent, and each of the claims 1 through 4, 6, and 8 through 15, the only remaining claims in the '564 reissue patent, thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

62. The '838 reissue patent, and each of the claims 1 through 15 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

63. The '253 reissue patent, and each of the claims 5 and 7, the only remaining claims of the '253 reissue patent, thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

Second Defense
(Noninfringement of the '564, '838, and '253 Reissue Patents)

64. Lupin Limited's drospirenone and ethinyl estradiol tablets do not infringe any valid and enforceable claim of the '564 reissue patent.

65. Lupin Limited's drospirenone and ethinyl estradiol tablets do not infringe any valid and enforceable claim of the '838 reissue patent.

66. Lupin Limited's drospirenone and ethinyl estradiol tablets do not infringe any valid and enforceable claim of the '253 reissue patent.

Third Defense
(Limitation of Remedies)

67. The remedy of an injunction or other equitable relief sought by Plaintiffs in its Complaint is unavailable to Plaintiffs in this action.

COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff Lupin Limited brings the following Counterclaims against Plaintiff/Counterclaim-Defendants Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. (collectively "Bayer") for a declaratory judgment that the '652, '338, '395, '326, and '931 patents and the '564, '838, and '253 reissue patents are invalid and not infringed by the Lupin Limited drospirenone and ethinyl estradiol tablets that are the subject of ANDA No. 20-1661 ("Lupin Limited's drospirenone and ethinyl estradiol tablets").

THE PARTIES

1. Counterclaim-Plaintiff Lupin Limited is corporation organized and existing under the laws of India having a place of business at Laxmi Towers "B" Wing, 5th Floor, Bandra Kurla Complex, Mumbai 400 051, India, and has a registered office at 159 C.S.T. Road, Kalina, Santacruz (East), Mumbai 400 098, India.

2. Upon information and belief, Counterclaim-Defendant Bayer Schering Pharma AG is a corporation organized under the laws of the Federal Republic of Germany, having its principal place of business in Müllerstrasse 178, 13353 Berlin, Germany.

3. Upon information and belief, Counterclaim-Defendant Bayer HealthCare Pharmaceuticals Inc. is a corporation organized under the laws of the State of Delaware, having its principal place of business at 6 West Belt, Wayne, New Jersey 07470.

BACKGROUND

4. Lupin Limited filed ANDA No. 20-1661 with the FDA seeking approval to market Lupin Limited's drospirenone and ethinyl estradiol tablets, referencing the approved NDA for YAZ®. The ANDA provides data showing that Lupin Limited's drospirenone and ethinyl estradiol tablets are bioequivalent to YAZ®, which is the subject of Bayer's NDA No. 21-676.

5. Bayer listed U.S. Patent Nos. 5,569,652 ("the '652 patent"), 5,798,338 ("the '338 patent"), 6,787,531 ("the '531 patent"), 6,933,395 ("the '395 patent"), 6,958,326 ("the '326 patent"), 6,987,101 ("the '101 patent"), 7,163,931 ("the '931 patent"), RE 37,564 ("the '564 reissue patent"), RE 37,838 ("the '838 reissue patent"), RE 38,253 ("the '253 reissue patent") in the Orange Book in connection with NDA No. 21-676 for YAZ®. By listing these patents, Bayer maintains that the patents claim YAZ®, or a method of using the drug, and that a suit for infringement could reasonably be brought against any generic manufacturer that attempts to seek approval to market a generic version of YAZ® before any of the aforementioned patents expire. *See* 21 U.S.C. § 355(b)(1)-(c)(2).

6. In 2008, the '531 patent was held invalid due to obviousness in *Bayer Schering Pharma AG v. Barr Labs., Inc.*, Civil Action No. 05-cv-2308, 2008 WL 628592 (D.N.J. Mar. 3,

2008). This decision was later affirmed by the Federal Circuit. *Bayer Schering Pharma AG v. Barr Labs., Inc.*, 575 F.3d 1341 (Fed. Cir. 2009).

7. Because Lupin Limited seeks FDA approval to market Lupin Limited's drospirenone and ethinyl estradiol tablets before the expiration of each of the '652, '338, '531, '395, '326, and '931 patents and the '564, '838, and '253 reissue patents, Lupin Limited's ANDA No. 20-1661 includes a paragraph IV certification for each of the aforementioned patents.

8. On or about June 2, 2010, Lupin Limited provided Bayer the statutorily-mandated notice letter of its paragraph IV certification on each of these patents. This notice letter included a detailed statement of the factual and legal bases for its opinion that, *inter alia*, the '652, '338, '531, '395, '326, and '931 patents and the '564, '838, and '253 reissue patents are invalid and/or not infringed by Lupin Limited's drospirenone and ethinyl estradiol tablets. The submission to the FDA of an ANDA containing a paragraph IV certification constitutes a technical act of infringement.

JURISDICTION AND VENUE

9. Lupin Limited re-alleges and incorporates by reference the allegations of paragraphs 1-8.

10. Plaintiffs have brought an action against Lupin Limited for allegedly infringing the '564, '838, and '253 reissue patents. There exists an actual case or controversy between Lupin Limited and Plaintiffs as to Lupin Limited's alleged infringement of the '564, '838, and '253 reissue patents.

11. There further exists an actual case or controversy between Lupin Limited and Plaintiffs as to the '652, '338, '395, '326, and '931 patents based on Bayer's listing of these patents in the Orange Book in connection with NDA No. 21-676 for YAZ®.

12. This Court has subject matter jurisdiction over a counterclaim for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a) and 1367, based on an actual controversy between Lupin Limited and Counterclaim Defendants Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. arising under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq*.

13. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) & (c) and 1400(b). Venue also is proper as a result of the filing of the present action by Plaintiffs against Lupin Limited in this judicial district.

LUPIN LIMITED IS ENTITLED TO DECLARATORY JUDGMENT

14. On July 15, 2010, Bayer filed the present lawsuit in this Court against Lupin Limited and Lupin Pharmaceuticals, Inc. alleging patent infringement of the '564, '838, and '253 reissue patents only by Lupin Limited's filing of ANDA No. 20-1661 for a generic version of YAZ®.

15. Bayer did not bring a lawsuit alleging infringement of the '652, '338, '395, '326, and '931 patents by Lupin Limited's filing of ANDA No. 20-1661 for a generic version of YAZ®. But by listing these patents in the Orange Book in connection with NDA No. 21-676 for YAZ®, Bayer maintains that the patents claim YAZ®, or a method of using YAZ®, and that a suit for infringement could reasonably be brought against any ANDA applicant that attempts to seek approval to market a generic version of YAZ® before any of the aforementioned patents expire. *See* 21 U.S.C. § 355(b)(1)-(c)(2). Bayer's listing of the '652, '338, '395, '326, and '931 patents in the Orange Book in connection with NDA No. 21-676 creates the requisite justiciable case or controversy and subject matter jurisdiction for a generic manufacturer that makes a paragraph IV certification on these patents to bring a declaratory judgment action.

16. A generic manufacturer, like Lupin Limited, that has submitted an ANDA containing a paragraph IV certification on a patent is entitled to bring and maintain a declaratory judgment action against the NDA holder/patent holder on that patent if the following have occurred: (1) 45 days have elapsed since the paragraph IV certification was received by the NDA holder/patent holder; (2) neither the NDA holder nor the patent holder has filed a suit for patent infringement on the patent subject to the paragraph IV certification within the 45-day period; and (3) an offer of confidential access to the ANDA is included in the notice of paragraph IV certification provided to the NDA holder/patent holder. *See* 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc).

17. Because Lupin Limited has provided the offer to confidential access to its ANDA pursuant to 21 U.S.C. § 355(i)(5)(C)(i)(III), and Bayer did not sue Lupin Limited on the '652, '338, '395, '326, and '931 patents within 45 days of receiving Lupin Limited's notice of paragraph IV certification, Lupin Limited is statutorily permitted to bring and maintain a declaratory judgment action against Bayer pursuant to 21 U.S.C. § 355(j)(5)(C).

18. Lupin Limited further requires a court decision of non-infringement and/or invalidity on the '652, '338, '395, '326, and '931 patents to prevent it from risking infringement liability on these patents if (and when) it begins marketing its generic version of YAZ® before any of these patents expire. This harm can be alleviated through a declaration of patent certainty on non-infringement and/or invalidity from this Court on the '652, '338, '395, '326, and '931 patents.

19. On November 5, 2007, Bayer filed a lawsuit in this Court against Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. (collectively "Watson") (the "Watson action") alleging infringement of the '531 patent and the '564 and '838 reissue patents by Watson's filing of an ANDA for a generic version of YAZ®.

20. On August 1, 2008, Bayer filed a lawsuit in this Court against Sandoz, Inc. alleging infringement of the '564 and '838 reissue patents by Sandoz' filing of an ANDA for a generic version of YAZ®. On November 4, 2008, this lawsuit was consolidated with the Watson action (the "Watson-Sandoz action").

21. On March 18, 2009, a Consent Judgment of Non-Infringement was entered in the Watson-Sandoz action, which stipulated that Sandoz' ANDA did not infringe the '338, '395, '326, '101, and '931 patents.

22. On September 22, 2009, a Consent Judgment of Non-Infringement was entered in the Watson-Sandoz action, which stipulated that Watson's ANDA did not infringe the '338, '395, '326, and '931 patents.

First Claim for Relief

(Declaration of Invalidity of the '564 Reissue Patent)

23. Lupin Limited incorporates the allegations set forth in paragraphs 1-22 of the Counterclaims as if fully set forth herein.

24. The '564 reissue patent, including claims 1 through 4, 6, and 8 through 15, the only remaining claims, thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

25. There is an actual case or controversy as to the invalidity of claims 1 through 4, 6, and 8 through 15, the only remaining claims, of the '564 reissue patent.

Second Claim for Relief

(Declaration of Noninfringement of the '564 Reissue Patent)

26. Lupin Limited incorporates the allegations set forth in paragraphs 1-22 of the Counterclaims as if fully set forth herein.

27. Lupin Limited's drospirenone and ethinyl estradiol tablets do not infringe any valid and enforceable claim of the '564 reissue patent.

28. There is an actual case or controversy as to the infringement of claims 1 through 4, 6, and 8 through 15, the only remaining claims, of the '564 reissue patent.

Third Claim for Relief

(Declaration of Invalidity of the '838 Reissue Patent)

29. Lupin Limited incorporates the allegations set forth in paragraphs 1-22 of the Counterclaims as if fully set forth herein.

30. The '838 reissue patent, including claims 1 through 15 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

31. There is an actual case or controversy as to the invalidity of claims 1 through 15 of the '838 reissue patent.

Fourth Claim for Relief

(Declaration of Noninfringement of the '838 Reissue Patent)

32. Lupin Limited incorporates the allegations set forth in paragraphs 1-22 of the Counterclaims as if fully set forth herein.

33. Lupin Limited's drospirenone and ethinyl estradiol tablets do not infringe any valid and enforceable claim of the '838 reissue patent.

34. There is an actual case or controversy as to the infringement of claims 1 through 15 of the '838 reissue patent.

Fifth Claim for Relief

(Declaration of Invalidity of the '253 Reissue Patent)

35. Lupin Limited incorporates the allegations set forth in paragraphs 1-22 of the Counterclaims as if fully set forth herein.

36. The '253 reissue patent, including claims 5 and 7, the only remaining claims thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

37. There is an actual case or controversy as to the invalidity of claims 5 and 7, the only remaining claims, of the '253 reissue patent.

Sixth Claim for Relief

(Declaration of Noninfringement of the '253 Reissue Patent)

38. Lupin Limited incorporates the allegations set forth in paragraphs 1-22 of the Counterclaims as if fully set forth herein.

39. Lupin Limited's drospirenone and ethinyl estradiol tablets do not infringe any valid and enforceable claim of the '253 reissue patent.

40. There is an actual case or controversy as to the infringement of claims 5 and 7, the only remaining claims, of the '253 reissue patent.

Seventh Claim for Relief

(Declaration of Invalidity of the '652 Patent)

41. Lupin Limited incorporates the allegations set forth in paragraphs 1-22 of the Counterclaims as if fully set forth herein.

42. The '652 patent, including claims 1 through 27 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

43. There is an actual case or controversy as to the invalidity of claims 1 through 27 of the '652 patent.

Eighth Claim for Relief

(Declaration of Noninfringement of the '652 Patent)

44. Lupin Limited incorporates the allegations set forth in paragraphs 1-22 of the Counterclaims as if fully set forth herein.

45. Lupin Limited's drospirenone and ethinyl estradiol tablets do not infringe any valid and enforceable claim of the '652 patent.

46. There is an actual case or controversy as to the infringement of claims 1 through 27 of the '652 patent.

Ninth Claim for Relief

(Declaration of Invalidity of the '338 Patent)

47. Lupin Limited incorporates the allegations set forth in paragraphs 1-22 of the Counterclaims as if fully set forth herein.

48. The '338 patent, including claims 1 through 14 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

49. There is an actual case or controversy as to the invalidity of claims 1 through 14 of the '338 patent.

Tenth Claim for Relief

(Declaration of Noninfringement of the '338 Patent)

50. Lupin Limited incorporates the allegations set forth in paragraphs 1-22 of the Counterclaims as if fully set forth herein.

51. Lupin Limited's drospirenone and ethinyl estradiol tablets do not infringe any valid and enforceable claim of the '338 patent.

52. There is an actual case or controversy as to the infringement of claims 1 through 14 of the '338 patent.

Eleventh Claim for Relief

(Declaration of Invalidity of the '395 Patent)

53. Lupin Limited incorporates the allegations set forth in paragraphs 1-22 of the Counterclaims as if fully set forth herein.

54. The '395 patent, including claims 1 through 6 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

55. There is an actual case or controversy as to the invalidity of claims 1 through 6 of the '395 patent.

Twelfth Claim for Relief

(Declaration of Noninfringement of the '395 Patent)

56. Lupin Limited incorporates the allegations set forth in paragraphs 1-22 of the Counterclaims as if fully set forth herein.

57. Lupin Limited's drospirenone and ethinyl estradiol tablets do not infringe any valid and enforceable claim of the '395 patent.

58. There is an actual case or controversy as to the infringement of claims 1 through 6 of the '395 patent.

Thirteenth Claim for Relief

(Declaration of Invalidity of the '326 Patent)

59. Lupin Limited incorporates the allegations set forth in paragraphs 1-22 of the Counterclaims as if fully set forth herein.

60. The '326 patent, including claims 1 through 32 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

61. There is an actual case or controversy as to the invalidity of claims 1 through 32 of the '326 patent.

Fourteenth Claim for Relief

(Declaration of Noninfringement of the '326 Patent)

62. Lupin Limited incorporates the allegations set forth in paragraphs 1-22 of the Counterclaims as if fully set forth herein.

63. Lupin Limited's drospirenone and ethinyl estradiol tablets do not infringe any valid and enforceable claim of the '326 patent.

64. There is an actual case or controversy as to the infringement of claims 1 through 32 of the '326 patent.

Fifteenth Claim for Relief

(Declaration of Invalidity of the '931 Patent)

65. Lupin Limited incorporates the allegations set forth in paragraphs 1-22 of the Counterclaims as if fully set forth herein.

66. The '931 patent, including claims 1 through 52 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

67. There is an actual case or controversy as to the invalidity of claims 1 through 52 of the '931 patent.

Sixteenth Claim for Relief

(Declaration of Noninfringement of the '931 Patent)

68. Lupin Limited incorporates the allegations set forth in paragraphs 1-22 of the Counterclaims as if fully set forth herein.

69. Lupin Limited's drospirenone and ethinyl estradiol tablets do not infringe any valid and enforceable claim of the '931 patent.

70. There is an actual case or controversy as to the infringement of claims 1 through 52 of the '931 patent.

PRAYER FOR RELIEF

WHEREFORE, Lupin Limited prays that this Court enter a judgment against Plaintiffs:

1. Declaring that Lupin Limited does not infringe the claims of the '652, '338, '395, '326, and '931 patents and the '564, '838 and '253 reissue patents;

2. Declaring that the claims of the '652, '338, '395, '326, and '931 patents and the '564, '838 and '253 reissue patents are invalid;

3. Awarding Lupin Limited its costs and expenses incurred in this action;

4. Declaring that this case is an exceptional case under 35 U.S.C. § 285 and awarding Lupin its attorneys' fees, and

5. Awarding Lupin Limited any further additional relief as the Court deems just and proper.

Dated: September 27, 2010

/s/ James E. Whitmire
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